4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0564]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) and the guidance document entitled "Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Dietary Supplement Labeling Requirements and Recommendations Under the Dietary

Supplement and Nonprescription Drug Consumer Protection Act--(OMB Control Number 0910
0642)--Extension

In 2006, the DSNDCPA (Public Law 109-462, 120 Stat. 3469) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The DSNDCPA also amended the FD&C Act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer, or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the <u>Federal Register</u> of September 1, 2009 (74 FR 45221), FDA announced the availability of a guidance document entitled, "Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act." The guidance document contains questions

and answers related to the labeling requirements in section 403(y) of the FD&C Act and provides guidance to industry on the use of an explanatory statement before the domestic address or telephone number. The guidance document provides the Agency's interpretation of the labeling requirements for section 403(y) of the FD&C Act and the Agency's views on the information that should be included on the label. The Agency believes that the guidance will enable persons to meet the criteria for labeling that are established in section 403(y) of the FD&C Act.

FDA estimates the burden of this collection of information as follows:

Activity No. of No. of Total Annual Average Total Respondents Disclosures Disclosures Burden per Hours Disclosure per Respondent² 0.5 2,780 Domestic address or phone 1,460 5,560 3.8 number labeling requirement (21 U.S.C. 343(y)) FDA recommendation for 0.5 1,460 3.8 5,560 2,780 label statement explaining purpose of domestic

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

5,560

address or phone number

Total

The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although FDA exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. FDA estimates that all labels required to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act have been revised by the effective date. Thus, in succeeding years, the Agency estimates that the burden hours associated with the labeling requirements of section 403(y) of the FD&C Act and the Agency's recommendations on the use of an explanatory

There are no capital costs or operating and maintenance costs associated with this collection of information.

² Number has been rounded to the nearest tenth.

statement will apply only to new product labels. Based on the A.C. Nielsen Sales Scanner Data, FDA estimated that the number of dietary supplement SKUs for which sales of the products are greater than zero is 55,600. Assuming that the flow of new products is 10 percent per year, then approximately 5,560 new dietary supplement products will come on the market each year. FDA also estimates that there are about 1,460 dietary supplement manufacturers, re-packagers, relabelers, and holders of dietary supplements. Assuming the approximately 5,560 new products are split equally among the firms, then each firm would prepare labels for close to four new products per year (5,560 new products/1,460 firms is approximately 3.8 labels per firm). Thus, the estimated total annual disclosures are 5,560 (1,460 firms x 3.8 labels per year = 5,560).

The Agency expects that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed on their product labels. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.5 hour per product to comply with the requirement to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act. The total hour burden of this task is shown in row 1 of table 1.

FDA estimates that all firms will include an explanatory statement on the label, which lets consumers know the purpose of the domestic address or telephone number on the label of the dietary supplement product. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.5 hour per product to comply with the Agency's recommendations on the use of an explanatory statement. The total hour burden of this task is shown in row 2 of table 1.

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The total reporting hour burden is 5,560 hours, which equals the burden for the required

domestic address or telephone (2,780) plus the burden for the explanatory statement before the

domestic address or telephone number (2,780).

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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